U.S. Department of Justice

Carmen M. Ortiz
United States Attorney
District of Massachusetts

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Suite 9200
1 Courthouse Way
Boston, Massachusetts 02210

January 17, 2012

Brien T. O'Connor
Joshua S. Levy
Ropes & Gray
800 Boylston Street
Boston, MA 02199

Re: United States v. Stryker Biotech, LLC, 09-10330-GAO

Dear Counsel:

This letter sets forth the Agreement between the United States Attorney for the District of Massachusetts (the "U.S. Attorney") and Stryker Biotech, LLC ("Stryker Biotech").

1. Change of Plea

On January 17, 2012, Stryker Biotech shall plead guilty to the Superseding Information attached hereto as Exhibit A. The Superseding Information charges one count of misdemeanor misbranding of a medical device in violation of 21 U.S.C. §§331(k), 333(a)(1) and 352(f)(1). Stryker Biotech expressly and unequivocally admits that it committed the misdemeanor offense charged in the attached Superseding Information and is in fact guilty of the offense. Stryker Biotech agrees that it will not make any statements inconsistent with this explicit admission. Stryker Biotech agrees to waive venue, to waive any applicable statutes of limitations, and to waive any defects in the Superseding Information.

The U.S. Attorney agrees to dismiss Counts 1-13 of the Superseding Indictment against Stryker Biotech and all counts of the original Indictment against Stryker Biotech following payment of the agreed-upon criminal fine after the imposition of sentence.

2. Penalties

Stryker Biotech is subject to a fine of $200,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greatest. *See* 18 U.S.C. §§3571(c), (d). The gross gain resulting from the offense, and relevant conduct from other instances of misbranding between February 2006 and February 2008, is twelve and a half million dollars ($12,500,000). Thus the maximum fine is twenty-five million dollars ($25,000,000). With respect to the count of conviction, Stryker Biotech may be sentenced to a term of probation of not more than five (5) years. *See* 18 U.S.C. §3561(c)(2).

With respect to the count of conviction, Stryker Biotech shall pay a special assessment of $125. *See* 18 U.S.C. §3013(a)(1)(B).

3. Criminal Fine/Sentencing Guidelines

The parties agree that while the fine provisions of the United States Sentencing Guidelines ("U.S.S.G.") do not apply to organizational defendants for misdemeanor violations of the Food, Drug and Cosmetic Act, see U.S.S.G. §8C2.1, the agreed upon fine is consistent with those guidelines and takes into account Stryker Biotech's conduct under 18 U.S.C. §§3553 and 3572, as follows:

a. The parties agree that the base fine is $12,500,000, which is the pecuniary gain to the organization from the offense. *See* U.S.S.G. §§8C2.4(a), 8C2.3.

b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is six (6), which is determined as follows:

   i. Base culpability score is five (5) pursuant to U.S.S.G. §8C2.5(a);

   ii. Add three (3) points under U.S.S.G. §8C2.5(b)(3);

   iii. Deduct two (2) points under U.S.S.G. §8C2.5(g);

   iv. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of six (6) is 1.2 to 2.4;

   v. Thus, the advisory Guideline Fine Range, if applicable, would be $15,000,000 to $25,000,000. *See* U.S.S.G. §§8C.2.7(a)(b); 18 U.S.C. §§ 3571(c)(d).

4. Agreed Disposition

The United States and Stryker Biotech agree pursuant to Fed. R. Crim. P. 11(c)(1)(C) that the appropriate disposition of this case is as follows, and will result in imposition of a reasonable sentence that is sufficient, but not greater than necessary, taking into consideration all of the factors set forth in 18 U.S.C. §§3553(a) and 3572.

a. A criminal fine of $15,000,000 to be paid within five business days of the date of sentencing. The parties agree that this criminal fine amount will result in a reasonable sentence taking into consideration all of the factors set forth in 18 U.S.C. §§ 553(a) and 3572;

b. A mandatory special assessment of $125 pursuant to 18 U.S.C. §3013;

c. The parties further agree that complication and prolongation of the sentencing process that would result from an attempt to fashion a restitution order outweighs the need to provide restitution to any potential victims in this case given the difficulty of tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the product at issue would be extraordinarily difficult, if not impossible. *Cf.* 18 U.S.C. §3663(a)(1)(B)(ii). Accordingly, the United States agrees that it will not seek a separate restitution order as to Stryker Biotech as part of the resolution of the Superseding Information and the Parties agree that the appropriate disposition of this case does not include a restitution order; and

d. The United States agrees it will not seek a term of probation in light of the fact that Stryker Biotech's current operations do not include any sales and marketing activities, and it has no marketable products.

The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement in this paragraph regarding the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, Stryker Biotech:

i. Fails to admit a complete factual basis for the plea;

ii. Fails to truthfully admit its conduct in the offense of conviction;

iii. Falsely denies, or frivolously contests, relevant conduct for which Stryker Biotech is accountable under U.S.S.G. §1B1.3;

iv. Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which

Stryker Biotech is accountable under U.S.S.G. §1B1.3;

v. Engages in acts which form a basis for finding that Stryker Biotech has obstructed or impeded the administration of justice under U.S.S.G. §3C1.1; and/or

vi. Attempts to withdraw its plea.

Stryker Biotech expressly understands that it may not withdraw its plea of guilty unless the Court rejects this Agreement under Fed. R. Crim. P. 11(c)(5).

5. No Further Prosecution of Stryker Biotech LLC

Pursuant to Fed. R. Crim. P. 11(c)(1)(A), the United States Attorney agrees that, other than the charge in the attached Superseding Information, it shall not further prosecute Stryker Biotech for conduct which (a) falls within the scope of the Superseding Information; (b) was the subject of the investigation by the grand jury in Massachusetts; (c) was charged in the Superseding Indictment or initial Indictment; or (d) was known to the U.S. Attorney related to OP-1 and/or Calstrux prior to the date of execution of this agreement. This declination is expressly contingent on:

(1) the guilty plea of Stryker Biotech being accepted by the Court and not withdrawn;

(2) Stryker Biotech's performance of all of its obligations as set forth in this Agreement. If Stryker Biotech's guilty plea is not accepted by the court or is withdrawn for any reason, or if Stryker Biotech should fail to perform an obligation under this Agreement, this declination of prosecution shall be null and void.

If Stryker Biotech's guilty plea is not accepted by the Court or is withdrawn for any reason, or if Stryker Biotech should fail to perform any obligation under this Agreement, this declination of prosecution shall be null and void.

The United States Attorney expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Stryker Biotech LLC, in connection with the conduct described above, with the sole exception of any individual who has been immunized by the Court in the pending trial proceedings of United States v. Stryker Biotech, LLC, et al., 09-CR-10330-GAO.

6. Payment of Mandatory Special Assessment

Stryker Biotech agrees to pay the mandatory special assessment to the Clerk of Court on or before the date of sentencing.

7. Waiver of Right to Appeal and to Bring Other Challenge

a. Stryker Biotech has conferred with its attorneys and understands that it has the right to challenge its convictions in the United States Court of Appeals for the First Circuit ("direct appeal"). Stryker Biotech also understands that it may, in some circumstances, be able to challenge its conviction in a future proceeding. Stryker Biotech waives any right it has to challenge its conviction on direct appeal or in any future proceeding.

b. Stryker Biotech has conferred with its attorneys and understands that defendants ordinarily have a right to appeal their sentences and may sometimes challenge their sentences in future proceedings. Stryker Biotech understands, however, that once the Court accepts this Rule 11(c)(1)(C) plea agreement, the Court is bound by the parties' agreed-upon sentence. Stryker Biotech may not contest the agreed-upon sentence in an appeal or challenge the sentence in a future proceeding in federal court. Similarly, the Court has no authority to modify an agreed-upon sentence under 18 U.S.C. § 3582(c), even if the Sentencing Guidelines are later modified in a way that appears favorable to Defendant. Given that a defendant who agrees to a specific sentence cannot later challenge it, and also because Stryker Biotech desires to obtain the benefits of this Agreement, Stryker Biotech agrees that it will not challenge the sentence imposed in an appeal or other future proceeding. Stryker Biotech also agrees that it will not seek to challenge the sentence in an appeal or future proceeding even if the Court rejects one or more positions advocated by any party at sentencing.

c. The United States agrees that it will not appeal the imposition by the Court of the sentence agreed to by the parties as set out in Paragraph 4, even if the Court rejects one or more positions advocated by a party at sentencing.

8. Waiver of Hyde Amendment Claim

Stryker Biotech is aware that 111 Stat. 2440, 2520 (1997), the so-called "Hyde Amendment," authorizes courts in criminal cases to award to certain prevailing defendants attorneys' fees and other litigation expenses. In exchange for concessions made by the U.S. Attorney in this Agreement, Defendant voluntarily and knowingly waives any claim that Stryker Biotech might assert under this statute based in whole or in part on the U.S. Attorney's agreement in Paragraph 1 to dismiss counts 1-13 of the Superseding Indictment against Stryker Biotech and to dismiss all counts in the initial Indictment against Stryker Biotech.

9. Cooperation

Stryker Biotech shall furnish to law enforcement agents, upon request, all documents and records in its possession, custody or control relating to the criminal proceedings in the District of Massachusetts concerning OP-1 and Calstrux, and that are not covered by the attorney-client privilege or work product doctrine, unless such privileges are waived by Stryker Biotech or required to be waived by the Court in connection with further trial proceedings in United States v. Stryker Biotech, LLC, et al., 09-CR-10330-GAO.

10. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office.

11. Fed. R. Crim. P. 11(c)(1)(C) Agreement

Stryker Biotech's plea will be tendered pursuant to Fed. R. Crim. P. 11(c)(1)(C). Stryker Biotech cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith, this Agreement shall be null and void at the option of either the United States Attorney or Stryker Biotech.

Stryker Biotech retains the option to request sentencing by the District Court immediately following the Rule 11 plea hearing. The United States will not object if the Court decides to sentence Stryker Biotech immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Stryker Biotech understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

12. Civil and Administrative Liability

By entering into this Agreement, the United States does not compromise any civil or administrative liability, including but not limited to any tax liability which Stryker Biotech may have incurred or may incur as a result of its conduct and its plea of guilty to the attached Superseding Information.

13. Waiver of Defenses

If Stryker Biotech's guilty plea is not accepted by the Court for whatever reason, or is later withdrawn for whatever reason, or if Stryker Biotech breaches this Agreement, Stryker Biotech hereby waives, and agrees it will not interpose, if charges are filed within six months of the date on which such guilty plea is rejected or withdrawn or a breach is declared by the USAO, any defense to any charges brought against it which it might otherwise have under the

Constitution for double jeopardy, pre-indictment delay, any statute of limitations, or the Speedy Trial Act.

14. Breach of Agreement

If the U.S. Attorney determines that Stryker Biotech has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in its entirety by notifying Stryker Biotech, through counsel or otherwise, in writing. The United States may also pursue all remedies available under the law, even if it elects not to be released from its commitments under this Agreement. Stryker Biotech recognizes that no such breach by Stryker Biotech of an obligation under this Agreement shall be grounds for withdrawal of its guilty plea. Stryker Biotech understands that should it breach any material provision of this Agreement, the U.S. Attorney will have the right to use against Stryker Biotech before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by Stryker Biotech, and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation.

15. Corporate Authorization

Stryker Biotech's acknowledgment of this Agreement and execution of this Agreement on behalf of the corporation is attached hereto. Stryker Biotech shall provide to the U.S. Attorney and the Court a copy of a resolution of the board of directors of Howmedica Osteonics Corp., Stryker Biotech's sole member (the "Member"), affirming that has authority to enter into the Plea Agreement and has (1) reviewed the Superseding Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) the Board of the Member voted to enter into the proposed Plea Agreement; (4) the Board of the Member voted to authorize Stryker Biotech to plead guilty to the charge specified in the Superseding Information; and (5) the Board of the Member voted to authorize the authorized representative identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement. A copy of the resolution is attached hereto as Exhibit B. Stryker Biotech agrees that either a duly authorized representative or duly authorized corporate officer or a duly authorized attorney for Stryker Biotech, at the discretion of the Court, shall appear on behalf of Stryker Biotech and enter the guilty plea and will also appear for the imposition of sentence.

16. Who is Bound by Agreement

This Agreement is binding upon Stryker Biotech and the Office of the United States Attorney for the District of Massachusetts.

17. Complete Agreement

This Agreement and its attachments, together with the Side Letter Agreement with Stryker Corporation dated January 17, 2012 and its attachments, contains the complete agreement between the parties relating to the disposition of this case. No promises, representations, agreements or conditions have been entered into other than those set forth in this Agreement and its attachments, and the Side Letter Agreement and its attachments. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral. This Agreement can be modified or supplemented only in a written memorandum signed by the Parties or as agreed by the Parties on the record in court.

If this letter accurately reflects the Agreement entered into between the United States and your client, please have the authorized representative of Stryker Biotech sign the Acknowledgment of Agreement below. Please also sign as Witness and return the original of this letter to Assistant U.S. Attorney Jeremy Sternberg of the United States Attorney's Office of the District of Massachusetts.

Very truly yours,

Carmen M. Ortiz

CARMEN M. ORTIZ
UNITED STATES ATTORNEY
DISTRICT OF MASSACHUSETTS

By: Susan Winkler

JEREMY M. STERNBERG
SUSAN G. WINKLER
GREGORY NOONAN
Assistant U.S. Attorneys
District of Massachusetts

ACKNOWLEDGMENT OF AGREEMENT

As a Director and Authorized Representative of Howmedica Osteonics Corp., I am duly charged with the power and authority to manage, and direct the management of, the business and affairs of and to make decisions to be made by Stryker Biotech, L.L.C. ("Stryker Biotech"). I am authorized to execute this Plea Agreement on behalf of Stryker Biotech. I have been provided with this Plea Agreement and the attached Superseding Information in their entirety. I have discussed them fully in consultation with Stryker Biotech's attorneys and acknowledge that these documents fully set forth Stryker Biotech's agreement with the United States. Stryker Biotech further states that no additional promises or representations have been made to Stryker Biotech by any officials of the United States in connection with the disposition of this matter, other than those set forth in the Plea Agreement.

Dated: January 17, 2012

Tony M. McKinney
Authorized Representative of Stryker Biotech, L.L.C.

Dated: January 17, 2012

Brien T. O'Connor
Joshua S. Levy
Counsel for Stryker Biotech, L.L.C.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA,	)	Criminal No.
v.	)	Violation:
STRYKER BIOTECH, LLC,	)	21 U.S.C. §§331(k), 333(a)(1) and 352 (Misbranding)
Defendant.	)	

SUPERSEDING INFORMATION

The United States Attorney charges that:

General Allegations

At all times material to this Superseding Information, unless otherwise alleged:

The FDA and FDCA

1. The United States Food and Drug Administration ("FDA") was an agency of the United States government entrusted with responsibility for protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans were safe and effective for their intended uses and that the labeling of such medical devices bore true and accurate information. Pursuant to this statutory mandate, FDA regulated the manufacture, labeling, and shipment in interstate commerce of such devices.

2. Under the Federal Food, Drug and Cosmetic Act (Title 21, United States Code, §301-397, the "FDCA"), the term "device" included an instrument, apparatus, implant, machine . . . or other similar or related article . . . which is . . . intended for use in . . . the treatment or prevention of disease of man . . . or intended to affect the structure or any function of the body of

man . . . which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. §321(h).

3. The FDCA required every manufacturer of a new device to submit proposed written labeling to the FDA for approval. "Labeling" meant all labels and other written, printed or graphic matter "(1) upon any article or any of its containers or wrappers or (2) accompanying such article." 21 U.S.C. § 321(m).

4. Labeling for medical devices was required to contain both (1) adequate directions for use, and (2) adequate warnings, among other warnings, against unsafe methods or application as were necessary for the protection of users. 21 U.S.C. § 352(f).

5. A prescription medical device was "misbranded" if, among other things, its labeling lacked adequate directions for use and it did not qualify for an exemption to this requirement. 21 C.F.R. §§ 801.5, 801.109.

6. Introduction or delivery for introduction into interstate commerce of a misbranded medical device was prohibited by law. 21 U.S.C. § 331(a). In addition, the law prohibited the doing of any other act with respect to a medical device when the device was held for sale after shipment in interstate commerce that resulted in the device being adulterated or misbranded. 21 U.S.C. § 331(k).

The Defendant

7. **STRYKER BIOTECH, LLC** (hereinafter "**STRYKER BIOTECH**") was a limited liability corporation with a principal place of business in Hopkinton, Massachusetts.

STRYKER BIOTECH was a subsidiary of Stryker Corporation, a company whose shares were publicly traded on the New York Stock Exchange.

8. At all relevant times, **STRYKER BIOTECH** was engaged in the manufacture and sale of medical devices for human use, including medical devices for use in healing of fractured or broken bones, including: (a) OP-1 Implant, which was an implant to promote growth in certain long bone non-unions; (b) OP-1 Putty, which was a putty to promote bone growth in certain spinal fusions; and (c) Calstrux, which was a bone void filler for surgically created bone defects or bone defects resulting from traumatic injury. **STRYKER BIOTECH** shipped these devices in interstate commerce from its manufacturing facility in New Hampshire to many states, including Massachusetts, California, Florida, Texas, North Carolina, New York, Ohio, Michigan and others.